

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

IN RE APPLICATION OF: Yoshinori NAOE, et al.

SERIAL NO: 10/508,958

GAU: 1617

FILED: December 12, 2005

EXAMINER: CARTER, K. D.

FOR: DEPSIPEPTIDE FOR THERAPY OF KIDNEY CANCER

**INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR 1.97**

COMMISSIONER FOR PATENTS  
ALEXANDRIA, VIRGINIA 22313

SIR:

Applicant(s) wish to disclose the following information.

**REFERENCES**

- ☒ The applicant(s) wish to make of record the reference(s) listed on the attached form PTO-1449. Copies of the listed reference(s) are attached, where required, as are either statements of relevancy or any readily available English translations of pertinent portions of any non-English language reference(s).
- ☒ Online credit card payment is being made in the amount required under 37 CFR §1.17(p).

**RELATED CASES**

- ☒ Attached is a list of applicant's pending application(s), published application(s) or issued patent(s) which may be related to the present application. In accordance with the waiver of 37 CFR 1.98 dated September 21, 2004, copies of the cited pending applications are not provided. Cited published and/or issued patents, if any, are listed on the attached PTO form 1449.
- ☐ Online credit card payment is being made in the amount required under 37 CFR §1.17(p).

**CERTIFICATION**

- ☐ Each item of information contained in this information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement.
- ☐ No item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to the knowledge of the undersigned, having made reasonable inquiry, was known to any individual designated in 37 CFR §1.56(c) more than three months prior to the filing of this statement.

**DEPOSIT ACCOUNT**

- ☒ Please charge any additional fees for the papers being filed herewith and for which no check or credit card payment is enclosed herewith, or credit any overpayment to deposit account number 15-0030.

Respectfully submitted,

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	Docket No.: 259908US0X PCT	Serial No.: 10/508,958
LIST OF RELATED CASES CITED BY APPLICANT UNDER 37 CFR 1.56	Inventor: Yoshinori NAOE, et al.	
	Filing Date: December 12, 2005	Group: 1617

**LIST OF RELATED CASES**

<u>Examiner Initial</u>	<u>Docket No.</u>	<u>Serial or Patent Number</u>	<u>Filing or Issue Date</u>	<u>Patent App. Publication No.</u>	<u>Inventor or Applicant</u>
	0018-0561-0	4,977,138	12/11/90		OKUHARA, et al.
	232863US0PCT	7,056,884	06/06/06		NAKAJIMA, et al.
	249030US0PCT	10/486,833	02/20/04	US2005/0191713 A1	SASAKAWA, et al.
	259908US0XPCT*	10/508,958	12/12/05	US2006/0135413 A1	NAOE, et al.
	276709US0PCT	10/546,285	05/31/06		SASAKAWA, et al.
	255118US0	7,056,883	06/06/06		ITO, et al.
	PER CLIENT	11/370,363	03/08/06	US2006/0223747 A1	ITO, et al.
	259545US0	10/948,288	09/24/04	US2005/0070467 A1	NAOE, et al.
	266735US0	11/064,292	02/24/05	US2005/0187149 A1	NAOE, et al.
Examiner	Date Considered				
*Present Application; listed for information NFO/sbs					

Docket No: 259908US0XPCT  
Serial No: 10/508,958

#### STATEMENT OF RELEVANCY

The data report listed as reference AW on the attached Form PTO-1449 represents data prepared by a joint assignee of the present application. These data relate to an *in vitro* anti-cancer screening in the Screening Service on its website. In the data, the NIH discloses Results from the National Cancer Institute Human Tumor Cell Line Screen of "NSC630176" which is the compound of the present invention.

This disclosure includes data against kidney cancer. These data bear a date-stamp of April 11, 2001 and have since been updated. The data is no longer available from the website. However, the data available presently from the web-site is that as of September, 2003. The linked URL is as follows:

[http://dtp.nci.nih.gov/dtpstandard/servlet/dwindex?searchtype=NSC&chemnameboolean=and  
&outputformat=html&searchlist=630176&tSubmit=Submit](http://dtp.nci.nih.gov/dtpstandard/servlet/dwindex?searchtype=NSC&chemnameboolean=and&outputformat=html&searchlist=630176&tSubmit=Submit)

These data show that the compound of the present invention shows good anti-cell proliferation activity *in vitro* against various kinds of cancer cells. However, this does not mean that the compound of the present invention can be used for the treatment of all such various kinds of cancer cells *in vivo*. While the results of similar *in vitro* screening of a large number of compounds are disclosed on the website of NIH, only a small number of the compounds have overcome the problems of bioavailability and toxicity and shown good activity *in vivo*. Accordingly, *in vivo* or clinical effects of the compound of the present invention are not obvious from the above-mentioned *in vitro* data.